URITEST 10 510(K) Summary

K052719

Prepared: November 1, 2006

Submitter: ARJ Medical, Inc

Address: 209 State Street
Oldsmar, FL 34677

DEC - 5 2006

Contact Person: Aaron Behar
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Trade Proprietary Name:

URITEST 10 Urinalysis Reagent Strips

Common/Usual Name:

Urinalysis Test Strips

Classification Names:

Urinary glucose (non-quantitative) test system (21 CFR 862.1340) – Class II
Urinary bilirubin and its conjugates (non-quantitative) test system (21 CFR 862.1115) – Class I
Ketones (non-quantitative) test system (21 CFR 862.1435) – Class I
Specific Gravity test (not classified in 21 CFR 862 or 864) – proposed Class I
Occult blood test (21 CFR 864.6550) – Class II
Urinary pH (non-quantitative) test system (21 CFR 862.1550) – Class I
Urinary protein or albumin (non-quantitative) test system (21 CFR 862.1645) – Class I
Urinary urobilinogen (non-quantitative) test system (21 CFR 862.1785) – Class I
Nitrite (non-quantitative) test system (21 CFR 862.1510) – Class I
Leukocyte peroxidase test (21 CFR 864.7675) – Class I

Legally marketed devices which we are claiming equivalence:

Bayer Corporation MULTISTIX 10 SG Reagent Strips

Device Description:

URITEST 10 Urinalysis Reagent Strips provide qualitative and semi-quantitative for pH, specific gravity, ketones. blood, protein, nitrite, leukocytes, glucose, bilirubin, and urobilinogen in urine. URITEST 10 Urinalysis Reagent Strips are firm plastic, dry reagent strips. The reagent areas are dipped into the urine sample and read visually according to a color chart or are read instrumentally with a Bayer® Family of Clinitek Urine Analyzers. The results are available within 120 seconds. To obtain optimal results, it is necessary to use fresh, well-mixed and uncentrifuged urine.

Intended Use:

ARJ Medical URITEST 10 Urinalysis Reagent Strips are for single use in professional near patient (point-of-care) facilities and centralized laboratory locations by medical technologists both read visually and on the Bayer Family of Clinitek Analyzers. .

Assessment of Performance:

The performance of URITEST 10 Urinalysis Reagent Strips was studied in a clinical laboratory setting. The strips were read visually and instrumentally using the Family of Bayer Clinitek Urine Analyzers. The results were compared to results obtained from Bayer MULTISTIX 10 SG reagent strips. The studies demonstrated that professional users in centralized and point-of-care (POC) hospital, clinical and doctor's office setting can obtain valid urinalysis test results.

Conclusion:

URITEST 10 Urinalysis Reagent Strips provide 10 reagent tests of urinalysis that are similar in composition and performance to reagent tests currently provided by devices on the U.S. market. URITEST 10 Urinalysis Reagent Strips are suitable for use in point-of-care (POC) settings. ARJ Medical studies showed that URITEST 10 Urinalysis Reagent Strips provide test results consistent with laboratory methods and performance comparable to that of Bayer MULTISTIX 10 SG Reagent Strips in POC, hospital, and clinical settings.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Aaron Behar
ARJ Medical, Inc.
209 State Street
Oldsmar, FL 34677

DEC - 5 2006

Re: k052719
Trade/Device Name: URITEST 10 Urinalysis Reagent Strips
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult blood test
Regulatory Class: Class II
Product Code: JIO, JIL, CDM, JJB, JIN, JIR, JMT, LJX, CEN
Dated: November 1, 2006
Received: November 3, 2006

Dear Mr. Behar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

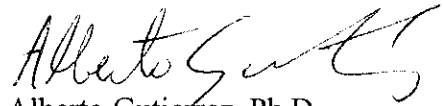
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number: (Applied For)

Device Name: URITEST 10 Urinalysis Reagent Strips

Indications for Use:

URITEST 10 Urinalysis Reagent Strips provide qualitative and semi-quantitative tests for glucose, bilirubin, ketones (acetoacetic acid), specific gravity, blood, pH, protein, urobilinogen, nitrites, and leukocytes in urine. Test results may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and bacteriuria.

ARJ Medical URITEST 10 Urinalysis Reagent Strips are for single use in professional near patient (point-of-care) facilities and centralized laboratory locations by medical technologists both read visually and on the Bayer Family of Clinitek Analyzers. The strips are intended of use in screening at-risk patients to assist diagnosis in the following areas:

Kidney Function
Urinary Tract infections
Carbohydrate metabolism
Liver Function
Acid-Base balance
Urine Concentration

Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K052719